PB87-110300

Guidance for the Reregistration of Pesticide Products Containing Cryolite as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Jun 83

U.S. Department of Commerce
National Technical Information Service
NTIS

50277-501

REPORT DOCUMENTATION PAGE | 1. REPORT NO. | 2. | 3. Recipient's Accession No. PB87 110300/AS

4. Title and Subtitle
Guidance for the Reregistration of Pesticide Products Containing CRYOLITE as the Active Ingredient.

5. Report Date
Issued JUNE 1983

6.

7. Author(s)
EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No.
540/RS-83- 026

9. Performing Organization Name and Address
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, SW
Washington, D. C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement
Publicly Available

19. Security Class (This Report)
Unclassified

21. No. of Pages
165

20. Security Class (This Page)
Unclassified

22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

PB87-110300

GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

CRYOLITE

AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

June 1983

EPA 540/RS-83-026

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

Table of Contents

Section		Page
I.	Introduction	1
II.	Regulatory Position and Rationale	3
III.	Requirement for Submission of Generic Data	14
IV.	Requirement for Submission of Product-Specific Data	34
V.	Submission of Revised Labeling and Packaging Information	35
	A. Label Contents	35
	1. Product Name	35
	2. Company Name and Address	35
	3. Net Contents	35
	4. Product Registration Number	35
	5. Producing Establishment Registration Number	36
	6A Ingredient Statement	36
	6B Pounds Per Gallon Statement	36
	7. Front Panel Precautionary Statements	36
	7A Child Hazard Warning Statements	37
	7B Signal Word	37
	7C Skull and Crossbones and Word Poison	37
	7D Statement of Practical Treatment	37
	7E Referral Statement	37
	8. Side/Back Panel Precautionary Labeling	37
	8A Hazard to Humans and Domestic Animals	38
	8B Environmental Hazard	38
	8C Physical or Chemical Hazard	38
	9 Misuse Statement	39
	10A Storage and Disposal Block	39
	10B Directions for Use	39
	B. Collateral Information	39
VI.	Instructions for Submission	40

APPENDICES

III-1	Bibliography.	41
III-2	FIFRA §3(c)(2)(B) Summary Sheet	45
III-3	Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data. . . .	46
IV-1	Product Specific Data Report (End-Use Products) . . .	47
V-2	Table of Labeling Requirements.	49
V-3	Physical/Chemical Hazards Labeling Statement.	53
V-5	Storage and Disposal Instructions	54

Note: Appendices V-1, V-4, and V-6 are not germane to this document and are not included.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), as amended in 1978, directs the Environmental Protection Agency (EPA) to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth certain of the requirements for registration and reregistration of all manufacturing-use products (MPs) containing the subject chemical as the sole active ingredient. These requirements include: that certain scientific data be submitted and that certain standards of toxicity, composition, labeling, and packaging be met. Registrants of MPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document and with the requirements contained in subsequent information from EPA about compliance with certain data support requirements.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

This guidance document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

II. Regulatory Position and Rationale

A. Introduction

This Chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on manufacturing-use products (MUPs) containing the insecticide cryolite. The Agency's position is based on an evaluation of all registered uses and products containing cryolite. This document also considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as well as Federal registrations granted or pending under Section 3 of the FIFRA. Finally, this document sets forth the data requirements that must be met to register MUP products covered by this Standard.

This document addresses registration requirements for MUPs (containing cryolite) and their intermediaries. Cryolite MUPs that differ appreciably from those described here may require amendments to the Standard.

B. Chemical Description and Use Profile

Cryolite is the common name for sodium fluoaluminate or sodium aluminofluoride (given variously as Na_3AlF_6, $3NaF.AlF_3$, AlF_6Na_3). The Chemical Abstracts Service (CAS) number is 15096-52-3 or 1344-75-8 and the EPA chemical code number is 075101.

Cryolite was first used as an insecticide in 1929. Cryolite acts as a stomach poison and is used predominantly on grapes, lettuce and melons. However, it is also registered for use on a number of other crops such as beans, some cole and cucurbit crops, tomatoes, peppers, strawberries, citrus, and certain deciduous tree fruits. The principal pests controlled on grapes are omnivorous leaf-roller, grape leaffolder, and orange tortrix as well as cutworms and other foliar feeders. The main target pests on head lettuce and other crops include cabbage looper, beet armyworm, and corn earworm. Cryolite may be applied by aerial or ground techniques as a spray or dust.

Open literature indicates that technical grade cryolite may be the naturally occurring fluoride of sodium and aluminum called "natural cryolite" or it may be the manufactured material of similar composition called "synthetic cryolite." Natural cryolite may be white, black, purple or violet and "synthetic cryolite" is white. Cryolite (both forms) is a solid with melting points of 1000°C for synthetic and 1009°C for natural cryolite. The compound appears to have low water solubility. However, the data in the literature provide a range of solubility values, therefore a water solubility determination is required on natural and synthetic cryolite.

Tolerances have been established for residues of cryolite on a number of crops; however, many of these crops are not presently listed on registered product labeling. Those crops

with an established tolerance that do not appear on registered product labeling will be acceptable for registration under this Standard, provided the data requirements outlined in Tables A and B of this document are fulfilled and support use on the crop. Residues of cryolite are measured as combined fluoride and may result from application of natural or synthetic cryolite.

C. Regulatory Position

Based on a review and evaluation of all available data and other relevant information on cryolite, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing cryolite may be registered for sale, distribution, and use, subject to the terms and conditions specified in this Standard.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the use of cryolite specified in this Standard. However, gaps in the data base preclude the completion of the Agency's risk assessment on this chemical.

3. Registrants must provide or agree to develop additional data, as specified in Tables A and B attached to this guidance document, in order to maintain existing registrations or to permit new cryolite registrations.

4. Tolerance reassessment is normally a part of the Registration Standard review process. However, the Agency will defer its reassessment of this compound until essential data on residues and toxicology tests are available. Specifically, the Agency is not able to establish a valid "No Observable Effect Level" (NOEL) or to determine an "Acceptable Daily Intake" (ADI) for cryolite.

D. Regulatory Rationale

The Agency has determined that it should continue to allow the registration of cryolite for the following reasons:

1. No toxicological hazards of concern have been identified in the studies reviewed for this Standard. The sequential testing approach is being applied to this compound because the chemical properties are unique. Therefore, after review of the studies listed in this Standard, additional subchronic and chronic studies may be required. Refer to Table A and B for initial data requirements and information regarding the Data Call-In process.

2. Existing evidence does not suggest that current tolerances would result in residue levels that will expose the public to unreasonable adverse effects. The fluoride acceptable daily intake (ADI), and maximum permissible daily intake (MPI) have not been determined and a comparison to the theoretical maximum residue contribution (TMRC) cannot be made at this time.

3. The Agency consludes that little meaningful data would result from the usual tests required by the guidelines for registration, subpart B Section 158.130. Therefore, most Environmental Fate requirements are not being requested for this Standard. However, hydrolysis and leaching studies are being required to define the potential for aquatic contamination.

4. From available wildlife studies, Agency scientists are able to assess the toxicity of cryolite to several terrestrial and aquatic test organisms. Cryolite is practicially non-toxic to bobwhite quail and mallard ducks in subacute doses; however, the hazards to birds, fish and aquatic invertebrates may be greater than previously supposed. These questions will be resolved by studies required by this Standard. Label warnings required by this Standard should protect fish and wildlife from known hazards.

5. Available data on human poisoning incidents indicate that the majority of cases cited in the Pesticide Incident Monitoring System (PIMS) from November 28, 1979, through October 29, 1981, appeared to be the result of misuse or accident.

6. The Agency cannot cancel or withhold registration merely because data are missing or inadequate (see Sections 3(c)(2)(B), 3(c)(7) and Section 6 of FIFRA). Rather, publication of this Standard provides a mechanism for identifying data needs, and registration under the Standard allows for the

upgrading of labels during the period when the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of cryolite.

E. Criteria for Registration Under this Standard

To be covered by this Standard, products must:

- contain cryolite,
- bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. This includes making a commitment to fill data gaps on a schedule specified by the Agency.

Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Standard, technical grade products must contain cryolite as the sole active ingredient. The Agency cannot at this time establish an appropriate percent of cryolite

in a technical grade product since there are no technical grade products currently registered. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and manufacturing-use products containing cryolite for any acute toxicity category, provided that the labeling of those products bears appropriate precutionary statements.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing cryolite may be labeled for formulation only into end-use products for domestic and non-domestic terrestrial outdoor food use on apples, apricots, asparagus,* beans, beets, blackberries, blueberries (huckleberries), boysenberries, broccoli, brussel sprouts, cabbage, cantalope, cauliflower, collards, corn, carrots, cranberries, cucumber, dewberries, eggplants, grapes, grapefruit, kale, kohlrabi, kumquat, lemon, lettuce, lime, loganberries, melons, mustard, nectarines, okra, orange, peaches, peanuts, pears, peas,

*Since there is no tolerance for asparagus, a petition for tolerance must be submitted to support registration for use on asparagus.

peppers, plums, pumpkins, quinces, radish, raspberries, rutabagas, strawberry, squash, tangelo, tangerine, tomato, turnips, watermelons, youngberries; and for domestic/non-domestic terrestrial outdoor non-food use on ornamental plants, ornamental trees and ornamental woody shrubs.

End-use products formulated from products registered under this Standard may be wettable powders or dusts, for either aerial or ground application.

G. Required Labeling

All technical grade and manufacturing-use products containing cryolite must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Use Pattern Statements

The labels of all manufacturing-use products must bear the intended end-use(s) of the formulated products to be prepared from the manufacturing-use products. All manufacturing-use products must contain one or more of the following statements:

For formulation into end-use insecticide products intended only for:

- Terrestrial domestic outdoor food use in home gardens on (specify food crops),
- Terrestrial domestic outdoor non-food crop use on ornamental plants, ornamental trees and ornamental woody shrubs,
- Terrestrial non-domestic food use on (specify food crops),
- Terrestrial non-domestic outdoor non-food crop use on ornamental plants, ornamental trees, and ornamental woody shrubs.

2. Precautionary Statements

Labels for all MUP products containing cryolite must bear statements reflecting the acute human toxicity of the compound. The guidance package provides an updated list of all precautionary statements which must appear for each type of product. In addition to the required precautionary statements, the following environmental hazard warnings must appear on manufacturing-use labels:

> Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance contact your regional office of the EPA.

H. Tolerance Reassessment

Cryolite has been accepted for use on many crops and tolerances have been issued (40 CFR 180.145) for residues of flourine in or on those crops. The general data base supporting those tolerances is not complete (Refer to Tables A and B for data requirements). Specific residue data are still missing for some crops and must be submitted to the Agency. The Agency will reassess all cryolite tolerances after the necessary toxicology and residue data are received.

The established tolerance for grapes (7 ppm) is supported by adequate residue data [grapes and raisins (washed), GS0087012, GS0087016 and GS0087017]. However, additional residue data are required to support established tolerances

for food crops other than grapes and raisins as listed under Section F, number 3, use patterns, of this document. The established tolerance for lettuce (7 ppm) is not fully supported by the available residue data [lettuce GS0087018]. Additional data will be needed to support the use of cryolite on lettuce. Refer to residue chemistry table A. Since there is no tolerance for asparagus, a petition for tolerance must be submitted to support registration for use on asparagus. Further, there are no data available on the processing of commodities other than raisins. Residue data are required to ascertain the need for food additive tolerances for those processed commodities specified in Table A. Livestock feeding studies are required to ascertain the extent of carryover (if any) into meat, milk, poultry and eggs, and the need to establish tolerances for these commodities.

Applicants seeking registration of cryolite on additional food or feed sites for which no tolerance has been established must submit residue data which support the establishment of a new tolerance or which justify an exemption from the requirement for a tolerance.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines [2/], or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

---

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

---

*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A - 1a
GENERIC DATA REQUIREMENTS FOR NATURAL CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
Section 158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Partial	GS0087004 GS0087005 GS0087006	Yes[2]/
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No		Yes
Physical and Chemical Characteristics:				
63-2 - Color	TGAI	Partial	GS0087005 GS0087008	Yes[2]/
63-3 - Physical State	TGAI	Yes	GS0087005	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes

1/ Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
2/ A general updating of information on natural cryolite and the presence of absence of chiolite is needed.
3/ Data must be submitted by December, 1983.

TABLE A - 1a
GENERIC DATA REQUIREMENTS FOR NATURAL CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[4]/
Section 158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Partial	GS0087004 GS0087005	Yes[2]/
63-12- pH	TGAI	No		Yes
63-13- Stability	TGAI	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	Choice	No		Yes[3]/

1/ Composition: TGAI - Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Resolution of conflicting solubility data in the literature is needed.
3/ The Agency will require a sample if need arises.
4/ Data must be submitted by December, 1983.

TABLE A - 1b
GENERIC DATA REQUIREMENTS FOR SYNTHETIC CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[4]/
Section 158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	GS0087012*[2]/	Yes[3]/
61-2 - Description of Beginning Material and Manufacturing Process	TGAI	Yes	GS0087012*[2]/	Yes[3]/
61-3 - Discussion of Formation of Impurities	TGAI	Yes	GS0087012*[2]/	Yes[3]/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Yes	GS0087012*[2]/	Yes[3]/
Physical and Chemical Characteristics:				
63-2 - Color	TGAI	Yes	GS0087012*[2]/	Yes[3]/
63-3 - Physical State	TGAI	Yes	GS0087012*[2]/	Yes[3]/
63-4 - Odor	TGAI	Yes	GS0087012*[2]/	Yes[3]/
63-5 - Melting Point	TGAI	Yes	GS0087012*[2]/	Yes[3]/
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	GS0087012*[2]/	Yes[3]/

1/ Composition: TGAI = technical grade of the active ingredient; PSI = pure active ingredient.
2/ This satisfied the data requirement for the technical grade synthetic cryolite used in the formulation of the product currently registered under EPA Registration No. 4581-116.
3/ Data are needed on each technical grade of synthetic cryolite other than that described in footnote 2/.
4/ Data must be submitted by December, 1983.
*/ DATA submitted by Pennwalt Corporation. These data may be compensable.

TABLE A - 1b
GENERIC DATA REQUIREMENTS FOR SYNTHETIC CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[5]/
Section 158.120 Product Chemistry (Continued)				
63-8 - Solubility	TGAI or PAI	Yes	GS0087012*[2]/	Yes[3]/
63-12- pH	TGAI	Yes	GS0087012*[2]/	Yes[3]/
63-13 Stability	TGAI	Yes	GS0087012*[2]/	Yes[3]/
Other Requirements:				
64-1 - Submittal of Samples	Choice	No	-	Yes[4]/

1/ Composition: TGAI - Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ This satisifies the data requirement for the technical grade synthtic cryolite used in the formulation of the product currently registered under EPA Registration No. 4581-116.
3/ Data are needed on each technical grade of synthetic cryolite other than described in footnote 2/.
4/ The Agency will require a sample if need arises.
5/ Data must be submitted by December, 1983
* Data submitted by Pennwalt Corporation. These data may be compensable.

TABLE A - 2
GENERIC DATA REQUIREMENTS FOR SYNTHETIC CRYOLITE

Data Requirement	Composition and Use pattern[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
Section 158.155 Residue Chemistry				
171.2 - Cehmical Identity - Natural	A,H	Partial	GS0087005 GS0087008 GS0087004	Yes[8]
- Synthetic	A,H	Yes	GS0087012*[11]	Yes[12]
171.3 - Directions for Use[9]	A,H			
171.4 - Nature of the Residue				
- Livestock	A,H	No		Yes[3]
171.4 - Residue Analytical Method	A,H	Yes	GS0087011	No
171.4 - Magnitude of the Residue				
- Crop field trials				
- Crops[4][7]	A,H	No		Yes[4]
- Grapes	A,H	Yes	GS0087016*[13] GS0087017*	No
- Lettuce	A,H	Partial	GS0087018	Yes[10]
- Processed Food/Feed	A,H	No		Yes[5]
- Raisins	A,H		GS0087017	No
- Meat/milk/poultry/eggs	A,H	No		Yes[6]

* Data submitted by Pennwalt Corporation. These data may be compensable.

1/ Composition of the material to be tested is technical grade unless otherwise specified in footnotes. The use patterns are coded as follows: A=Terrestial, Food Crop; B=Terrestrial, outdoor domestic/nondomestic non-food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-food; G=Forestry; H=Domestic Outdoor terrestrial food crop; I=Indoor.

2/ Data must be submitted by June, 1986.

3/ The fate of cryolite, sites of deposition and deposition in qualitative terms is needed for animals (livestock).

4/ Residue data (with information on the use pattern when appropriate) are needed on the following crops: apples and pears, (pome fruit grouping except crabapples), beans, lima beans and peas, (one succulent & one dried variety of each for bean grouping except soybean); broccoli, cabbage and mustard greens, (cole crop grouping): corn (grain, forage, fodder, and silage); cucumber, cantelopes or muskmelon and summer squash, (fruiting vegetable, cucurbits grouping); sweet orange, lemon and grapefruit, (citrus grouping); Tomatoes, eggplants and peppers, (fruiting vegetables grouping); blackberries, blueberries (huckleberries), boysenberries, raspberries, youngberries, and loganberries (small fruits grouping); and individually, asparagus; carrots; radish; turnips (root & tops); cranberry; strawberries; peaches; apricot; nectarine; plum; beets; rutabaga (with or without tops); beet greens alone; okra; quinces; and peanuts.

5/ Residue Data are needed on the following processed commodities: Apple pomace, (wet and dry), apple juice, bean cannery waste, citrus, (peel, oil, dried pulp and molasses), corn (oil and milled fractions) mustard seed, tomato pomace, (wet and dry, juice, puree, catsup). A food additive petition must be submitted for processed commodities when residues exceed the level of the tolerance for the raw agricultural commodity.

6/ Livestock feeding studies are required to ascertain the extent of residue carryover (if any) into these commodities and to ascertain the need for tolerances for these commodities.

7/ A petition for tolerance must be submitted to support registration of asparagus since there is no established tolerance for asparagus.

8/ A general updating of information on natural cryolite and the presence or absence of chiolite is needed.

9/ The amount, frequency, and time of application of the pesticide chemical must be submitted to support current established tolerances.

10/ These data submitted in support of the 24(c) registration on lettuce with a 24-day PHI are not adequate to support either this 24(c) use nor the federally registered use on lettuce, which prohibits application after the seedling stage. These data indicate that a petition to increase the present tolerance of 7 ppm to 20 ppm would be required to support this 24(c) use. Residue data reflecting the directions for use would be needed to support the federally registered use (and existing tolorance of 7 ppm).

11/ This satisfies the data requirement for the technical grade of the synthetic cryolite used in the formulation of the product currently registered under EPA Registration No. 4581-116.

12/ Data are needed on each technical grade of synthetic cryolite other than that described in footnote 11/.

13/ All of the data cited (GS008716 and GS008717) are needed to satisfy this data requirement.

TABLE A - 3

GENERIC DATA REQUIREMENTS FOR CRYOLITE[4]/

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec 3(c)(2)(B)?[3]/
Section 158.130 Environmental Fate					
DEGRADATION STUDIES - LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A, B, H	No	-	Yes
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A, B, H	No	-	Yes

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.

3/ Data must be submitted no later than June, 1986.

4/ No other Environmental Fate studies are being required because the chemical and physical properties of cryolite are such that the usual Environmental Fate studies would not be expected to yield information useful to the regulatory decision.

TABLE A - 4

GENERIC DATA REQUIREMENTS FOR CRYOLITE

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[3]/
158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD50 - Rat	TGAI	A, B, H	Partial[5]/	GS0087013*	Yes[4]/[5]/[6]/
81-2 - Dermal LD50	TGAI	A, B, H	Yes	GS0087013*	No[6]/
81-3 - Inhalation LC50 - Rat	TGAI	A, B, H	Yes	GS0087013*	No[6]/
81-4 - Primary Eye Irritation - Rabbit	TGAI	A, B, H	Yes	GS0087013*	No[6]/
81-5 - Primary Dermal Irritation	TGAI	A, B, H	Yes	GS0087013*	No[6]/
81-6 - Dermal Sensitization	TGAI	A, B, H	No		Yes
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rat	TGAI	A, B, H	No		Yes
Dog	TGAI	A, B, H	No		Yes

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.

3/ Data must be submitted no later than December, 1983.

4/ Open literature references variously report the LD_{50} for cryolite from 200 to 10,000 mg/kg. These data reports may not represent contradictory data. Rather, they may reflect differences in crystalline makeup of the pesticide and thus, differences in absorption through the gut. Sodium aluminum fluoride is known to vary in color and elemental ratio. For this reason, and because no actual data are available, product specific studies are necessary.

5/ In order to satisfy acute oral data requirements using one dose level, test animals are to be dosed with at least 5 g/kg.

6/ These data are applicable to the active ingredient used in the formulation of the product registered under EPA Registration No. 4581-116. These data may be required to support technical grades of cryolite other than herein described.

*/ Data submitted by Pennwalt Corporation. These data maybe compensable.

GENERIC DATA REQUIREMENTS FOR CRYOLITE[4]/

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)
Section 158.135 Toxicology (Continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,H	No	-	Yes[4]/
83-1 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,H	NO	-	Yes[4]/
83-3 - Teratogenticity - Rat	TGAI	A,H	Partial	GS0087013*	Yes[4]/
Rabbit	TGAI	A,H	No	-	Yes[4]/
83-4 - Reproduction, 2-generation	TGAI	A,H	No	-	Yes[4]/
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,H	No	-	Yes[3]/
84-2 - Chromosomal Aberration	TGAI	A,H	No	-	Yes[3]/
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,H	No	-	Yes[3]/
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,H	Yes	GS0087013	NO

1/ Compposition: TGAI = Technical grade of the active ingredient.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.
3/ Data must be submitted no later than June, 1986.
4/ Chronic feeding two species, oncogenicity two species, two generation reproduction and othr subchronic studies, (a second rabbit teratology study may be required following submission and evaluation of rat subchronic, rat terratology, mutagenicity and residue data). If required, these studies would need to be submitted by the applicant within 48 months of notification.
5/ This study may be upgraded from supplemental to core minimum upon submission of a final report.
*/ Data submitted by Pennwalt Corporation. These data may be compensable.

TABLE A - 6

GENERIC DATA REQUIREMENTS FOR CRYOLITE[4]/

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[3]/
158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,H	No	-	Yes
71-2 - Avian Dietary LC_{50}	TGAI	A,B,H	Yes	00084001[5]/ 00084002	No
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,H	Yes	GS0003503	No
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,H	Yes	GS0003503	No
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,H	No	-	Reserved[4]/

1/ Composition: TGAI = Technical grade of the active ingredient.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.

3/ Data must be submitted by December, 1983.

4/ The Fish Early Life stage study is reserved pending results of the required Environmental Fate data hydrolysis and leaching studies. Note: items 71-3, 71-4, 71-5, 72-3, 72-5, 72-6 and 72-7 are not required because the chemical and physical properties of cryolite are such that usual studies would not be expected to yield information useful to the regulatory decision.

5/ All of the data cited (00087001 and 00084002) are needed to satisfy this data requirement.

TABLE A - 7

GENERIC DATA REQUIREMENTS FOR CRYOLITE

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?
158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B,H	Yes	00036935*	No
141-2 - Honey bee - Toxicity of residues on foliage	TEP	A,B,H	No	-	No[4]/
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A,B,H	No	-	No[4]/
141-4 - Honey bee subacute feeding study	[Reserved][3]/				
141-5 - Field testing for pollinators	TEP	A,B,H	No	-	No[4]/

1/ Composition: TGAI = Technical grade of the active ingredient.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.

3/ Requirement is reserved pending development of test methods and/or pending decisions as to whether data would be required.

4/ Due to the low toxicity demonstrated by the Honey Bee acute contact LD_{50} these studies are not required (141-3 and 141-5).

*/ These data may be compensable.

TABLE A - 8

GENERIC DATA REQUIREMENTS FOR CRYOLITE

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?
158.155 Nontarget Insect (Continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	[Reserved][3]/				
142-2 - Acute insect life-cycle study	[Reserved][3]/				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved][3]/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	[Reserved][3]/				

1/ Composition: TGAI = Technical grade of the active ingredient.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; Forestry; H=Domestic Outdoor Terrestrial Food Crop; I=Indoor.

3/ Requirement is reserved pending development of test methods and/or pending decisions as to whether data would be required.

TABLE B - 9

PRODUCT SPECIFIC DATA FOR MANUFACTURING USE PRODUCTS CONTAINING CRYOLITE

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?
Section 158.135 Toxicology				
ACUTE TESTING:				
81-1 - Oral LD50 - Rat	MP	Partial[3]/	GS0087013*	Yes[1]/[2]/[4]/
81-2 - Dermal LD50	MP	Yes	GS0087013*	No[4]/
81-3 - Inhalation LC50 - Rat	MP	Yes	GS0087013*	No[4]/
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	GS0087013*	No[4]/
81-5 - Primary Dermal Irritation	MP	Yes	GS0087013*	No[4]/
81-6 - Dermal Sensitization	MP	No	-	Yes

1/ Refer to footnote #4 on Toxicology Table A, acute testing.
2/ Required data must be submitted by December, 1983
3/ In order to satisfy acute oral data requirements using one dose level, test animals are to be dosed with at least 5 g/kg.
4/ These data are applicable to the active ingredient used in the formulation of the product registered under EPA Registration No. 4581-116. These data may be required to support MP grades of cryolite other than herein described.
*/ Data submitted by Pennwalt Corporation. These data may be compensable.

TABLE B - 10a

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING NATURAL CRYOLITE

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[2]
Section 158.120 Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	MP	Partial[3]	GS0087004 GS0087005 GS0087008	Yes[3]
61-2 - Description of beginning materials and manufacturing process	MP	No		Yes
61-3 - Discussion of Formation of Impurites	MP	No	-	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	No	-	Yes
62-2 - Certification of Limits	MP	No	-	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	Partial	GS0087996	Yes[4]
Physical and Chemical Characteristics:				
63-2 - Color	MP	Partial	GS0087008 GS0087005	Yes[3]
63-3 - Physical State	MP	Yes	GS0087005	No
63-4 - Odor	MP	No		Yes
63-7 - Density, Bulk Density, or Specific Gravity	MP	No		Yes

1/ Composition: MP = Manufacturing-use product unless otherwise specified in footnotes.
2/ Data must be submitted by December, 1983.
3/ A general update of information on natural cryolite and the presence or absence of chiolite is needed.
4/ Existing AOAC, 12th ed. method in Sec 6.018 will determine total fluorine. A means of distinguishing cryolite from fluorine containing impurities (chiolite) will be needed.

TABLE B - 10a

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING NATURAL CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[2]/
Section 158.120 Product Chemistry (Continued)				
63-12 - pH	MP	Partial	GS0087005	Yes[3]/
63-14 - Oxidizing or reducing action	MP	No		Yes
63-16 - Storage Stability	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	Choice	No	-	Yes[4]/

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than December, 1983.

3/ A general updating of information on natural cryolite is needed.

4/ The Agency will require a sample if need arises.

TABLE B - 10b

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING NATURAL CRYOLITE

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[2]/
Section 158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	MP	Yes	GS0087012*[3]/	Yes[4]/
61-2 - Description of Beginning Materials and Manufacturing Process	MP	Yes	GS0087012*[3]/	Yes[4]/
61-3 - Discussion of Formation of Impurities	MP	Yes	GS0087012*[3]/	Yes[4]/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	MP	Yes	GS0087012*[3]/	Yes[4]/
62-2 - Certification of Limits	MP	Yes	GS0087012*[3]/	Yes[4]/
62-3 - Analytical Methods for Enforcement of Limits	MP	Yes	GS0087012*[3]/	Yes[4]/
Physical and Chemical Characteristics:				
63-2 - Color	MP	Yes	GS0087012*[3]/	Yes[4]/
63-3 - Physical State	MP	Yes	GS0087012*[3]/	Yes[4]/
63-4 - Odor	MP	Yes	GS0087012*[3]/	Yes[4]/
63-7 - Density, Bulk Density or Specific Gravity	MP	Yes	GS0087012*[3]/	Yes[4]/

[1]/ Composition: MP = Manufacturing-use product.

[2]/ Data must be submitted no later than December, 1983.

[3]/ This satisfies the data requirement for the MP synthetic cryolite used in the formulation of the product currently registered under EPA Registration No. 4581-116.

[4]/ Data are needed on each MP synthetic cryolite other than that described in footnote 3.

[5]/ Data submitted by Pennwalt Corporation. These data may be compensable.

TABLE B - 10b

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING NATURAL CRYOLITE

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Sec. 3(c)(2)(B)?[2]
Section 158.120 Product Chemistry (Continued)				
63-12 - pH	MP	Yes	GS0087012*[3]	Yes[4]
63-14 - Oxidizing or reducing action	MP	Yes	GS0087012*[3]	Yes[4]
63-16 - Storage Stability	MP	Yes	GS0087012*[3]	Yes[4]
Other Requirements:				
64-1 - Submittal of Samples	Choice	No	-	Yes[5]

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than December, 1983.

3/ This satisfies the data requirement for the MP synthetic cryolite used in the formulation of the product currently registered under EPA Registration No. 4581-116.

4/ Data are needed on each MP synthetic cryolite other than that described in footnote 3.

5/ The Agency will require a sample if need arises.

*/ Data submitted by Pennwalt Corporation. These data may be compensable.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. William H. Miller, Product Manager
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-2600

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author.

as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

CRYOLITE

Bibliography

00036935 Atkins, E.L., E.A. Greywood, and R.L. Macdonald (1975). Toxicity of Pesticides and Other Agricultural Chemicals to Honeybees. Laboratory Studies, University of California, Division Agric. Sci. Leaflet 2287. 38pp.

00084001 Fink, R. (1975) Final Report; Eight-day Dietary LC_{50}, Bobwhite Quail; Project No. 110-113. (Unpublished study received Mar. 4, 1975 under 1202-297; prepared by Truelow Farms, Inc., submitted by Puregro Co., Los Angeles, Calif.; CDL:222203-B.)

00084002 Fink, R. (1975) Final Report: Eight-day Dietary LC_{50} -- Mallard Ducks; Project No. 110-104. (Unpublished study received Mar. 4, 1975, under 1202-297; prepared by Truelow Farms, Inc., submitted by Puregro Co., Los Angeles, Calif.; CDL:222203-B.)

GS0003503 Johnson, W.W. and M.T. Finley - 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. U.S. Fish and Wildlife Service, Resource Publication 137. 98 pages.

GS0087004 Kirk-Othmer "Encyclopedia of Chemical Technology," 2nd Edition (1966).

GS0087005 Negherbon, W.O., "Handbook of Toxicology, Volume III, Insecticides, A Compendium," WADC Technical Report 55-16, (June 1959) United States Air Force.

GS0087006 "Official Methods of Analysis of the Association of official Analytical Chemists," 12th Edition (1975) Section 6.018.

GS0087008 The Merck Index, 9th Edition (1976).

GS0087011 "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Edition, Section 25.049.

GS0087012 The Pennwalt Corporation. Additional Data in Support of Application for Amended Registration of Krocide® Insecticide. (EPA Registration No. 4581-116) June 1982. (EPA Acc. No. 247607).

GS0087013 The Pennwalt Corporation. Data submitted by Agency request under the Data Call-In-Notice. February 4, 1983, (EPA Acc. No. 071392).

GS0087016 The Pennwalt Corporation. Additional Data in Support of Application for Amended Registration of Kryocide® Insecticide (EPA Registration No. 4581-116) June 1982. Grapes and Raisins. (EPA Acc. No. 247608).

GS0087017 Pennwalt Corporation. Additional Data in Support of Application for Amended Registration of Kryocide® Insecticide (EPA Registration No. 4581-116) (EPA Acc. No. 276434 - Grapes).

GS0087018 Pennwalt Corporation. Application for SLN Registration No. CA-810090 for Kryocide® Insecticide. April, 1982. (EPA Acc. No. 247554 - Lettuce).

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

Appendix IV-1
(continued)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED US PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions	Immediately before directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Producls (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene